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10/505,352	08/19/2004	Richard W LeVaughn	2G02.1-080 US	5981
23506 7590 03/04/2010 GARDNER GROFF GREENWALD & VILLANUEVA, PC 2018 POWERS FERRY ROAD SUITE 800 ATLANTA, GA 30339				
EXAMINER				
STOUT, MICHAEL C				
ART UNIT		PAPER NUMBER		
3736				
NOTIFICATION DATE		DELIVERY MODE		
03/04/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/505,352

Applicant(s)

LEVAUGHN ET AL.

Examiner

MICHAEL C. STOUT

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/09/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 69, 70 and 78-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 69, 70 and 78-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/505,352 filed on 2/20/2003 and is an action based on the merits of the application.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 02/21/2002, 2/21/2002 and 09/24/2002. It is noted, however, that applicant has not filed a certified copy of the 10208575.7 and 10245721.2 application as required by 35 U.S.C. 119(b).

Regarding the claim to priority of US provisional applications 60/287,639 and 60/411,834, however the provisional applications are filed in a language other than English. If the Applicant wishes to claim prior to above mentioned provisional applications, the Applicant must provide certified English translations in the present application or in previously filed provisional applications.

37 CFR 1.78(a)(5) states in part:

If the prior-filed provisional application was filed in a language other than English and both an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application, applicant will be notified and given a period of time within which to file, in the prior-filed provisional application, the translation and the statement. If the notice is mailed in a pending nonprovisional application, a timely reply to such a notice

must include the filing in the nonprovisional application of either a confirmation that the translation and statement were filed in the provisional application, or an amendment or Supplemental Application Data Sheet withdrawing the benefit claim, or the nonprovisional application will be abandoned. The translation and statement may be filed in the provisional application, even if the provisional application has become abandoned. Claim to domestic priority documents not in English must be accompanied by a certified translation see MPEP 706.02(b) and/or when necessary to overcome the date of a reference relied upon by the examiner, or when deemed necessary by the examiner, see 37 CFR 1.55.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

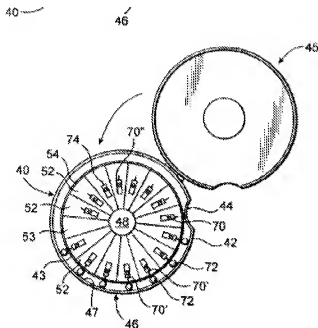
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-12, 17-20, 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US 6,228,100 B1) in view of Moerman et al. (US 6,706,159).

Regarding claims 1-3, 5-12 Schraga discloses a lancing device comprising: a housing (20); a cassette removably mounted to said housing (40, see Column 4, Lines 60-67),



said cassette comprising at least one lancet (70) having a lancet body (see Figure 1) and a protective cap (72); a piston (24, see Figure 2) for *propelling the lancet along a path of travel*, said piston having a lancet coupling portion (the downwardly depending segment 25, of the assembly 24 engages the lancet (Column 5, Lines 44-67 and Figure 2) for *releasably engaging and retracting the lancet* (See Column 5, Lines 26-43) to *separate the lancet body and the protective cap along a retraction portion of the path of travel of the lancet and thereafter advancing the lancet along the path of travel into a lancing position* (the italicized claim limitations are directed towards intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art, the piston is capable of retracting a

lancet body having a cap and forcing the cap to be removed by pulling the cap 72 against the hole 54 in Figure 2)

at least one guide member associated with each lancet (the cap removal device 90 is associated with all the lancets in the cassette, additionally as each lancet is indexed to have the cap removed the cap removal device is associated with each lancet for that process), the guide member being aligned transversely to the path of travel of the associated lancet within the cassette (guide posts surrounding channel 92 are positioned on a plane transverse/across/perpendicular to the path of travel of the lancet , see Figures 4 and 6, positioned within the cassette opening, see Figure 6 or the wall area surrounding the hole 54 shown in Figure 2) *for engaging the separated protective cap of the associated lancet to guide the protective cap out of the path of travel* (both features are capable of engaging the cap and separating it from the lancet body and guiding it transversely out of the path of travel) and

a retainer positioned within the cassette adjacent each said at least one guide member (the spacing gap defined between the shield assembly 42 and the lancet carrier which is *capable of retaining separated caps* 72, the spacing is next to located adjacent to either side of the openings 46 where the guide member is positioned as shown in Figure 6) *to retain the separated protective cap*. In regards to claim 2, the cassette further comprises a biasing element (94 comprises a hinge element) and the cassette further comprises at least one guide post engaging the protective cap (guide post on opposite sides of the notch 92, Figure 6).

The cassette comprises a plurality of the lancets radially arranged about an axis (see Figure 1) in a plane, best seen in Figure 2) wherein the piston propels the lancet along a path of travel within that plan, (see Figure 2) and the lancing device further comprises an advancing mechanism and wherein the cocking mechanism and the advancing mechanism are coupled together so that they operate together (see Column 6, Lines 65-67).

The cassette further comprises radially extending guides (guide regions 52) defining the path of travel of the lancet. Each lancet further comprises a resilient tongue extending from the lancet body.

Furthermore the cassette comprises an aperture through which the mount hub is 80 is positioned see Figure 2, which functions as an alignment indicator to properly align the firing unit and cassette, see Figure 5 and Figure 2. The biasing element moves the cap transversely out of the lancet path of travel best seen in Figure 6. And at least one recession (Figure 4 shows a recession formed between the guide channels 52 and wall 40 of the housing capable of retaining used lancet caps).

Scharaga fails to explicitly disclose the device wherein the cassette is mounted within the housing.

Moerman teaches a lancet device comprising a plurality lancets mounted within a housing 81.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Scharaga to include the lancets within a housing as taught by Moerman in order to provide a streamlined meter which

can be worn in the form of a wrist watch see Column 7, Lines 38-55 making the device easy to carry. Regarding claims 18 and 19 Moerman teaches a device said housing resembles a wristwatch housing (see Above), and further comprising a wristband (82) and also comprising sample collection and analysis media (sensor disk 84).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US 6,228,100 B1) in view of Moerman et al. (US 6,706,159) as applied to claim 1 above and in further view of Shichman et al. (US 6,197,041 B1).

Regarding claim 16, Schraga teaches a device wherein the lancet body and the piston comprise inter engaging coupling elements (see Column 4, Lines 25-55). One of ordinary skill in the art would recognize that connecting elements are often tapered to facilitate connection, (for example see US 4,750,851, abstract). Nevertheless, Shichman teaches a skin piercing device comprising a coupling portion (124c) having a tapered lead-in section for mounting to the distal end of a shaft 122.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Scharaga to include a tapered lead in section as taught by Shichman in order to facilitate the alignment of the connecting components.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US 6,228,100 B1) in view of Moerman et al. (US 6,706,159) as applied to claim 1 above and in further view of Lange et al. (US 5,554,166)

Regarding claim 16, Schraga teaches a device wherein the lancet body and the piston comprise inter engaging coupling elements (see Column 4, Lines 25-55). One of ordinary skill in the art would recognize that connecting elements are often tapered to facilitate connection. Lange teaches a skin piercing device comprising a coupling portion (61 and 60) having a tapered lead-in section for mounting to the distal end of a shaft see Figure 1.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Scharaga to include a tapered lead in section as taught by Lange in order to facilitate the alignment of the connecting components.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US 6,228,100 B1) in view of Moerman et al. (US 6,706,159) as applied to claim 3 above and in further view of Morita et al. (US 5,385,571 B1).

Scharaga teaches the device wherein a pair of guide posts (on either side of aperture 92) are slid ably engaged with protective cap to move the cap out of the path of travel of the lancet. Scharaga fails to disclose the device wherein the cap comprises a pair of recesses. Morita disclose a lancet cap having a pair of recesses (18). Therefore

it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Scharaga to include a cap recesses as taught by Morita in order to facilitate the removal of the cap by providing a weak point in the lancet body.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scharaga (US 6,228,100 B1) in view of Moerman et al. (US 6,706,159) as applied to claim 3 above and in further view of Ruppert et al. (US 5,152,775 B1).

Scharaga teaches the device wherein the at least one guide member comprises a pair of guide posts (on either side of aperture 92) are slidably engaged with protective cap to move the cap out of the path of travel of the lancet. Scharaga fails to disclose the device wherein the cap comprises a pair of recesses in opposed sides. Ruppert discloses a lancet cap having a pair of recesses (38 having a pair of recesses 39 the cap being removed when recesses sliding thru a pair of guide posts, Column 3, Lines 33-64). Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Scharaga to include a cap recesses as taught by Ruppert in order to facilitate the removal of the cap by providing a weak point in the lancet body by engaging the grooves with the guide posts.

Claims 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bobecker et al. (US 20040102803 A1).

Multiple embodiments are cited for the purpose of this rejection.

Regarding claim 1, Bobecker discloses a lancing device comprising: a housing (Figure 56a shows the lancet device comprising a housing);

a cassette removably mounted within said housing (the underside the housing 566 may also be hinged or otherwise removable to allow the insertion of cartridge 500 into the device, see [0153]), said cassette comprising at least one lancet having a lancet body and a protective cap (figures 66-70 show the cassette comprising a plurality of lancets, each lancet having a lancet body 708, [0166] and a cap 714, see Figure 67 and [0168]);

a piston (gripper 716 propels the lancet, see Figures 69d-69g and [0166]-[0167] and [0171]-[0173]) for propelling the lancet along a path of travel, said piston having a lancet coupling portion for releasably engaging and retracting the lancet to separate the lancet body and the protective cap along a retraction portion of the path of travel of the lancet, and thereafter advance the lancet along the path of travel into a lancing position (the driving member 716 is capable of engaging the lance and causing separation of the lancet body from the protective cap, Figures 69a-69l shows the griper engaging the lancet driving the lancet away from the protective cap and then engaging the cap with the lancet tip);

at least one guide member aligned transversely to the path of travel of the lancet within the cassette member (bar 730 aligned perpendicular to the lancet travel path see

Figure 69a and 69b and [0172]) for engaging the separated protective cap to guide the protective cap transversely out of the path of travel (see Figures 69f through 70); and

a retainer position within the cassette adjacent the at least one guide member to retain the separated protective cap (the cartridge comprises a retainer having a plurality of spring elements corresponding to the respective lancing elements which bias the cap out of the lancet path, see Figure 69F below the protective caps are mounted at the end of the spring element see Figure 69F and retain the cap when the cap is separated from the needle by 730) wherein the retainer and the protective caps comprising separate components.

Regarding claim 13, Bobecker further discloses the lancing device of Claim 8, wherein said cassette further a plurality of spring elements aligned for engagement with the protective caps of said plurality of lancets to move the protective caps out of the path of travel after separation of the protective cap from the lancet body (the cartridge comprises a retainer having a plurality of spring, one per lancet, elements corresponding to the respective lancing elements which bias the cap out of the lancet path, see Figure 69F below the protective caps are mounted at the end of the spring element see Figure 69F and retain the cap when the cap is separated from the needle by 730).

Regarding claim 14, Bobecker further discloses the lancing device of Claim 13, wherein said retainer further comprises a plurality of guide tongues (Figure 67 and 68

shows the cassette wherein each lancet as guide posts to help guide and contain the lancet, see also at least and [0165]-[0173]) for defining the path of travel of said lancets.

Regarding claim 15, Bobecker further discloses the lancing device of Claim 13, wherein each of said spring elements comprises a generally U-shaped loop, (each of the spring elements comprises a generally u-shaped loop, Figures 69* and see also Figure 65 a).

Regarding claim 78, Bobecker teaches a lancing device comprising: a housing (Figure 56a shows the lancet device comprising a housing); a cassette removably mounted within said housing (the underside the housing 566 may also be hinged or otherwise removable to allow the insertion of cartridge 500 into the device, see [0153]), said cassette comprising at least one lancet having a lancet body and a protective cap (figures 66-70 show the cassette comprising a plurality of lancets, each lancet having a lancet body 708, [0166] and a cap 714, see Figure 67 and [0168]);

a piston (gripper 716 propels the lancet, see Figures 69d-69g and [0166]-[0167] and [0171]-[0173]) for propelling the lancet along a path of travel, said piston releasably engaging the lancet and causing separation of the lancet body and the protective cap along at least a portion of the path of travel of the lancet (the driving member 716 is capable of engaging the lance and causing separation of the lancet body from the protective cap, Figures 69a-69l shows the griper engaging the lancet driving the lancet away from the protective cap and then engaging the cap with the lancet tip); wherein said cassette comprises a plurality of lancets radially arranged about an axis (Figure

66); and wherein said cassette further comprises a retainer having a plurality of spring elements extending therefrom (the cartridge comprises a retainer having a plurality of spring elements corresponding to the respective lancing elements which bias the cap out of the lancet path, see Figure 69F), said spring elements engaging the protective caps of said plurality of lancets (the protective caps are mounted at the end of the spring element see Figure 69F) *to move the protective caps out of the path of travel after separation of the protective cap from the lancet body*, the retainer and the protective caps comprising separate components (Bobecker in Figure 69H below shows the cap biasing being a unitary piece formed from separate components, a cap connected to a spring element and retainer).

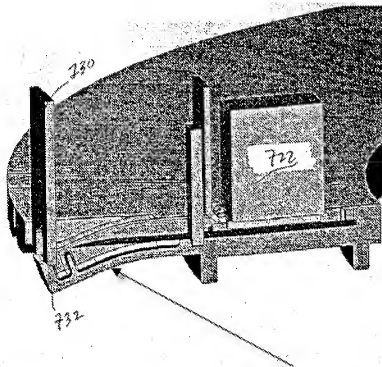


FIG - 694

Spring Element

Regarding claim 79, Bobecker teaches the device wherein said retainer further comprises a plurality of guide tongues (Figure 67 and 68 shows the cassette wherein each lancet as guide posts to help guide and contain the lancet, see also at least and [0165]-[0173]) for defining the path of travel of said lancets.

Regarding claim 80, Bobecker teaches the device wherein each of said spring elements comprises a generally U-shaped loop (each of the spring elements comprises a generally u-shaped loop, Figures 69* and see also Figure 65 a).

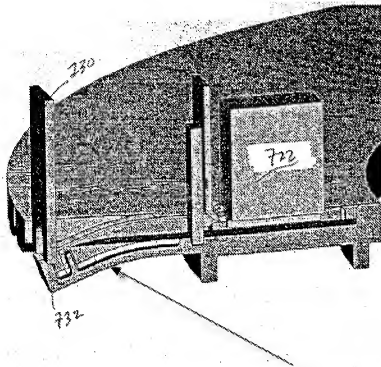


FIG - 694

Spring Element

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Response to Arguments

Applicant's arguments filed 7/17/2009 have been fully considered but they are not persuasive. The Applicants arguments are directed towards newly presented claim language which is addressed in the office action above.

In order to further prosecution the amended claim language is addressed below.
the guide member disclosed by

Regarding the limitations of the at least one guide member being associated with each lancet. As discussed above Schraga teaches a guide member which is attached to the cassette and its associated with all of the lancets, additionally when each lancet is indexed to have its cap removed the guide member is associated with the corresponding lancet. Limitations drawn to reciting each lancet having a separate individual corresponding at least one guide member, or a plurality of lancets and a plurality of guide members wherein each lancet has an individual corresponding at least

one of the guide members may further clarify different features between the applicants disclosure and the Scharaga reference.

Regarding the limitations of "the retainer and the protective caps comprising separate components.

Bobecker in Figure 69H below shows the cap biasing being a unitary piece formed from separate components, a cap connected to a spring element and retainer.

Limitations drawn to further clarify how the structure of the applicants cap biasing components over the unitary structure of Bobecker may further clarify different features between the applicants disclosure and the cited reference.

The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736